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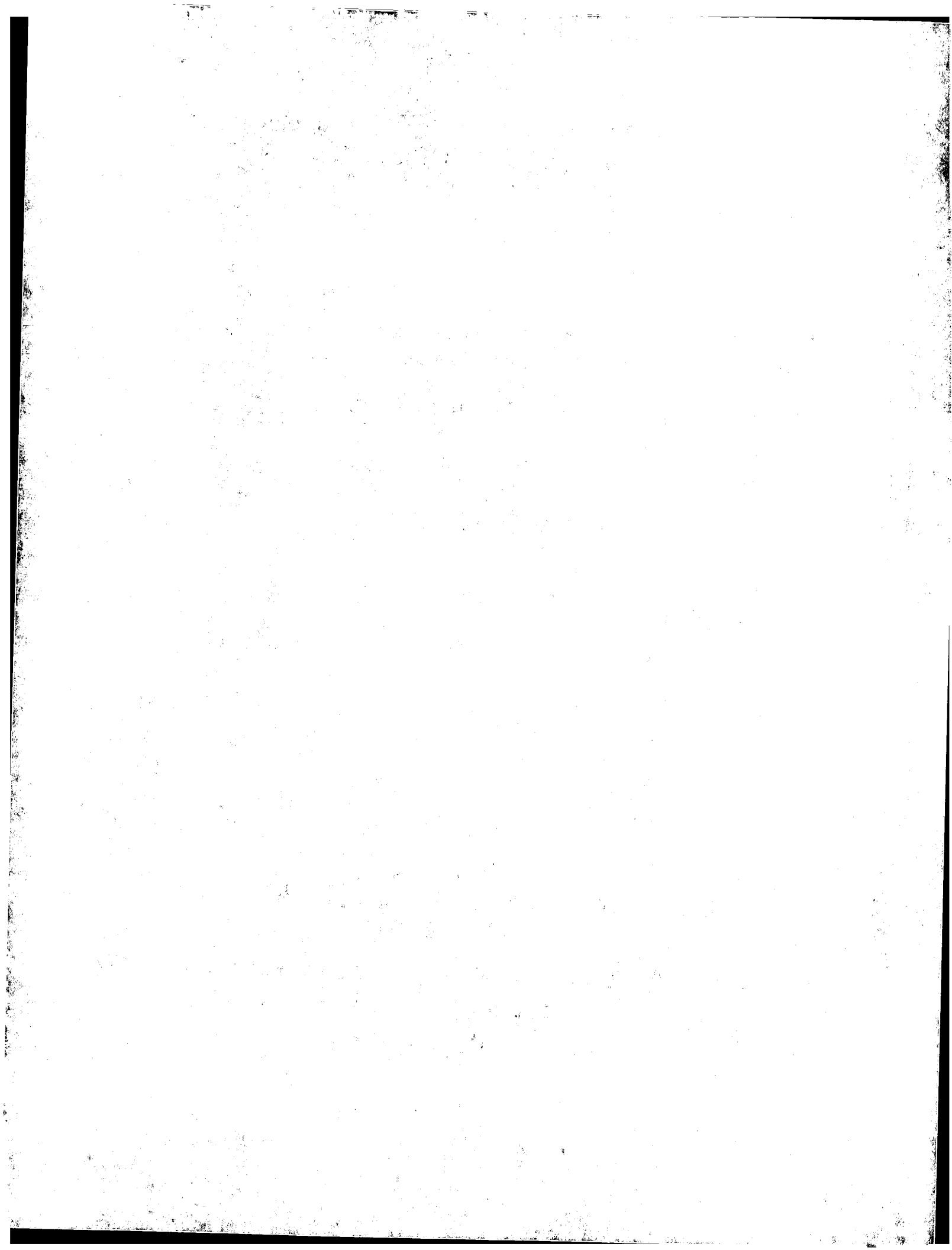
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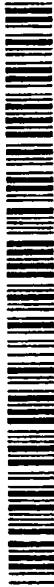
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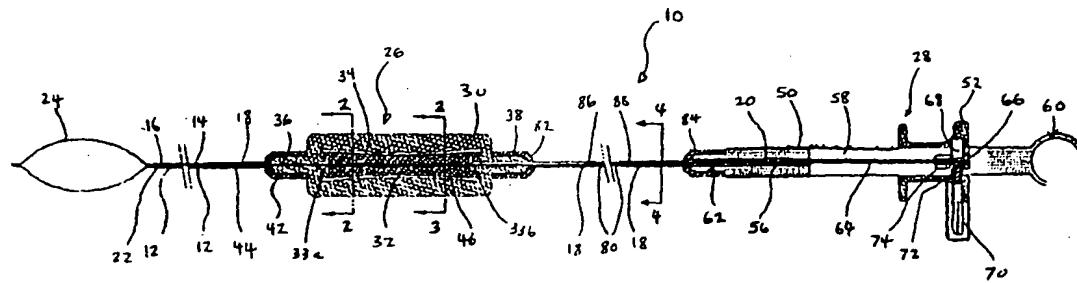
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09/369,724 6 August 1999 (06.08.1999) US*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*(71) Applicant: **BOSTON SCIENTIFIC CORPORATION**
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(54) Title: POLYPECTOMY SNARE INSTRUMENT

**WO 01/10321 A1**

(57) Abstract: A surgical snare instrument includes a first handle (26) capable of controlling the rotational position of the snare (24), and a second handle (28) adapted to control the opening and closing of the snare (24) and cauterization. The first handle (26) serves as a grippable element on the sheath (12) and contains a system which rotates the shaft (18), and consequently the snare (24), so that when the physician grasps the first handle (26), the physician is capable of steering the snare (24) by operating the first handle (26). In addition, the physician is also capable of positioning the entire sheath (12) relative to the endoscope by sliding the sheath (12) into and out of the working channel of the endoscope.

1 sheath begins to extend out of the distal end of the endoscope.
2 The physician then directs an assistant, who has control of the
3 handle of the snare instrument, to open the snare. The assistant
4 accomplishes this function by moving two portions of the handle
5 relative to each other. The physician then advances and retracts
6 the sheath into and out of the endoscope, while applying torque to
7 some portion of the instrument to position the snare loop over and
8 around a polyp. Once the snare loop is positioned around the
9 polyp, the physician orders the assistant to close the snare
10 around the polyp. Then, the physician or assistant energizes a
11 source of electrocautery current coupled to the shaft to
12 desiccate, sever, and cauterize the polyp. Finally, the polyp is
13 removed by withdrawing the snare (or, in some cases, the polyp is
14 retrieved by use of another instrument such as a biopsy forceps).
15 In a variation of the procedure, the physician uses suction
16 applied to a channel of the endoscope to remove the polyp or to
17 hold it to the end of the endoscope.

18

19 Prior art snare instruments have several problems. First, it
20 is difficult for the physician to precisely position the snare
21 because the physician relies on gripping the small, slippery
22 sheath over the shaft near where the sheath enters the endoscope
23 handle. Typically, it is necessary for the physician to
24 repeatedly push, pull, and torque the sheath and the shaft of the
25 instrument in order to achieve the desired position with the snare

assistant to coordinate the handle controls while the physician moves the jacket in and out of the endoscope. As a result, these instruments have not been widely accepted by physicians.

SUMMARY OF THE INVENTION

7 It is therefore an object of the invention to provide a snare
8 instrument which permits the physician to control all aspects of
9 positioning the snare loop relative to the polyp, while allowing
10 the assistant to perform the cauterizing and severing of the
11 polyp.

13 It is a further object of the invention to provide a snare
14 instrument which provides to the physician the means for advancing
15 and retracting the distal end of the snare instrument through the
16 endoscope, as well as rotating the snare, and which provides to
17 the assistant the means for extending and retracting the snare
18 loop from the sheath of the snare instrument.

19
20 It is another object of the invention to provide a snare
21 instrument in which the physician has direct and immediate control
22 of the entire instrument.

1 the sheath is adjacent to the distal end of an endoscope. The
2 physician's handle serves as a grippable element on the sheath and
3 contains a rotating means for rotating the shaft, so that when the
4 physician grips that handle the physician is capable of steering
5 (rotating) the snare by operating the rotating means. In
6 addition, the physician is also capable of positioning the entire
7 sheath relative to the endoscope by sliding the sheath into and
8 out of the working channel of the endoscope. The proximal handle
9 is operable by an assistant and permits longitudinal movement of
10 the shaft and snare and the application of a cautery current to
11 the shaft and snare.

12

13 According to other embodiments, the snare instrument is
14 provided with a connector which enables the snare instrument to be
15 fixed relative to an endoscope handle. Additionally, an
16 embodiment is also provided in which a single handle provides a
17 physician with means for advancing and retracting the sheath of
18 the snare instrument relative to the distal end of the endoscope,
19 means for advancing (opening) and retracting (closing) the snare
20 relative to the distal end of the sheath, and means for steering
21 (rotating) the snare to position the snare over a polyp. Since
22 the physician has direct and immediate control of the entire
23 instrument, the snare instrument obviates the need for an
24 assistant during the procedure, and improves the speed and
25 efficiency of the polypectomy procedure.

1 Fig. 7 is an enlarged cross-section through line 7-7 in
2 Fig. 5, at a location proximal of the key;

3
4 Fig. 8 is a broken section view of a third embodiment of the
5 snare instrument according to the invention;

6
7 Fig. 9 is an enlargement of the area between lines 9a-9a and
8 9b-9b in Fig. 8;

9
10 Fig. 10 is a broken section view of a fourth embodiment of
11 the snare instrument of the invention; and

12
13 Fig. 11 is a broken section view of a fifth embodiment of the
14 snare instrument of the invention.

15
16 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

17
18 Turning now to Fig. 1, a first embodiment of a surgical snare
19 instrument 10 according to the invention is shown. The snare
20 instrument 10 includes an elongate flexible tubular sheath 12
21 having a proximal end 14 and a distal end 16, a flexible shaft 18
22 having a proximal end 20 and a distal end 22 extending through and
23 axially movable relative to the sheath 12, a snare 24 coupled to
24 or formed at the distal end 22 of the shaft 18, preferably
25 adjacent the distal end 16 of the sheath 12, and first and second

1 The apertures 35 provide access to the knob 32, so that the knob
2 32 can be rotated relative to the body 30, e.g., by a physician.

3

4 A portion of the shaft 18 extending through the bore 40 of
5 the knob 32 is provided with a key 46; that is, a spline element
6 fixed on and about the shaft 18 or, alternatively, rigidly and
7 fixedly interposed between two portions of the shaft. The key 46
8 preferably has a rectangular shape but may have another non-
9 circular shape. The key 46 is slidably axially movable within the
10 bore 40. Therefore, the shaft 12 may be moved axially through the
11 bore 40 (and that is why the length of the knob 32 is preferably
12 at least as long as the distance of movement required to open and
13 close the snare). However, when the knob 32 is rotated relative
14 to the body 30, the key 46 within the bore 40 is rotated and,
15 consequently, the shaft 18 and snare 24 are rotated relative to
16 the sheath 12.

17

18 The distal handle assembly 28 is preferably positioned
19 approximately 210 cm from the distal end 16 of the sheath 12 for a
20 snare instrument 10 designed to be inserted into a 200 cm
21 endoscope. Thus, the physician can grip the body 30 in a manner
22 which permits rotating the knob 32 relative to the body, and hence
23 the snare 24 relative to the sheath 12, while using the body 30 as
24 a grip to axially position the snare instrument 10 within the
25 working channel of an endoscope.

1 Referring to Figs. 1 and 4, an electrically insulative
2 extension sheath 80 extends over the shaft 18 between the proximal
3 end 38 of the body 30 and the distal end 62 of the stationary
4 member 50, coupled, e.g., via flare-nut connections 82, 84. Thus,
5 there is a continuous outer connection joining, yet spacing apart,
6 the distal handle assembly 26 and the proximal handle assembly 28.
7 A stiffening sleeve 86 is preferably provided over the extension
8 sheath 80 at the proximal end 38 of the body 30, and another
9 stiffening sleeve 88 is preferably provided over the extension
10 sheath 80 at the distal end 62 of the stationary member 50.

11
12 In use, the physician introduces the snare instrument 10 into
13 the endoscope (not shown), typically by means of a port in the
14 endoscope handle which communicates with the working channel of
15 the endoscope. Then, the physician gives the proximal assistant's
16 handle 28 to the assistant. The physician then grips the body 30
17 of the distal physician's handle 26 of the snare instrument and
18 uses it to position the distal end 16 of the sheath 12 adjacent to
19 the polyp to be excised. The physician then instructs the
20 assistant to extend the snare, which is performed by moving the
21 spool member 52 relative to the stationary member 50. The
22 physician then uses the distal handle 26 to simultaneously axially
23 position and rotate the snare over the polyp. Then, the physician
24 instructs the assistant to close the snare and sever the polyp,
25 using cautery if desired. In this manner, the physician controls

1 1.25 inches). It should be noted that if the key 146 has a
2 substantial length (e.g., 0.75 inch), the body 130 and knob 132
3 can be made even shorter, since it is necessary for only a portion
4 of the key 146 to be engaged with the non-circular bore 140 of the
5 knob shaft 192 at any time.

6
7 In addition, while the first embodiment describes a shaft 18
8 that is monolithic and continuous from the snare 24 to the
9 proximal handle assembly 28, the shaft may alternatively be a
10 composite structure. Specifically, referring to Figs. 8 and 9,
11 according to a third embodiment of the invention, the
12 straightened, torsionally-stiff, camber-free section of the shaft
13 218 need only extend from the snare to the knob 232. A swivel
14 joint 290 may be interposed on the shaft 218 between the knob 232
15 and the proximal handle assembly, and join the shaft 218 to a
16 flexible or stiff proximal shaft extension 292 which extends to
17 the proximal handle assembly. The proximal end 294 of the shaft
18 218 is preferably formed into an enlarged section, i.e., a head
19 296, or a separate, enlarged head may be attached to the proximal
20 end of the shaft. A swivel tube 298, preferably made of a
21 malleable alloy, such as brass or stainless steel, is provided
22 over the head 296. A distal end 299 of the swivel tube 298 is
23 swaged or crimped to form a loose fit on the shaft 218, while
24 being small enough to retain the head 296. The swivel tube 298 is
25 placed onto the shaft 218 such that the head 296 is trapped inside

1 includes a coupling fitting 352 which is couplable to the port of
2 the endoscope, and a connector 354 which is slidably movable, yet
3 capable of being secured in a position, relative to the coupling
4 fitting 352. The connector 354 has a proximal end 356 which is
5 threadably coupled to the distal end 336 of the body 330.

6

7 The coupling fitting 352 includes a cylindrical block 358
8 having an axial bore 360, and a tubular nosepiece 362 secured in
9 the axial bore 360. The connector 354 includes a stepped bore 364
10 having a relatively large central portion 366, and relatively
11 smaller proximal and distal portions 368, 370. The central
12 portion 366 of the stepped bore 364 is sized to permit relative
13 axial movement over the block 358. The distal portion 370 of
14 stepped bore 364 is sufficiently large to permit axial movement of
15 the connector 354 over the nosepiece 362. A locking screw 372
16 extends radially into the central portion 366 of the stepped bore
17 364 of the connector 354 such that the screw 372 may be rotated to
18 tighten against the block 358 to lock the connector 354 axially
19 relative to the block. The proximal end 314 of the sheath 312
20 extends through the nosepiece 362 and block 358 and is fixedly
21 coupled in the proximal portion 368 of the stepped bore 364.
22 Other aspects of the fourth embodiment are substantially as
23 described above with respect to the first embodiment.

24

1 opening and closing functions. To that effect, a sliding spool
2 assembly 428 for longitudinally moving the shaft 418 relative to
3 the sheath 412 may be substantially rigidly fixed to the proximal
4 end 438 of the body 430. For example, a distal end 462 of a
5 stationary member 450 of the spool assembly 428 may be threadably
6 mated with the proximal end 438 of the body 430. The spool
7 assembly is preferably otherwise substantially as described with
8 respect to proximal handle assembly 28 of the first embodiment of
9 the invention.

10
11 The resulting device is fixedly couplable relative to an
12 endoscopic handle and provides to the physician the following
13 controls: a means for controllably advancing, retracting, and
14 setting the sheath of the snare instrument relative to the distal
15 end of the endoscope; a means for advancing (opening) and
16 retracting (closing) the snare relative to the distal end of the
17 sheath; and a means for steering (rotating) the snare to position
18 the snare over a polyp. Since the physician has direct and
19 immediate control of the entire instrument, the snare instrument
20 obviates the need for an assistant during the procedure, and
21 improves the speed and efficiency of the procedure.

22
23 There have been described and illustrated herein several
24 embodiments of a surgical snare instrument. While particular
25 embodiments of the invention have been described, it is not

1 and the snare relative to the distal end of the sheath. Moreover,
2 while a particular nosepiece has been described for use in the
3 fourth and fifth embodiment, it will be appreciated that other
4 nosepieces enabling stable coupling of the snare handle to an
5 endoscope handle may be used. For example, a threaded connector
6 capable of threading into or over a port on the endoscope handle
7 may be used. Also, in the fourth and fifth embodiment, the mount
8 and the body may be integrally formed or molded, and in the fifth
9 embodiment, the body and the proximal sliding spool assembly may
10 be integrally formed or molded. In addition, it will be
11 appreciated that aspects of the various embodiments may be
12 combined. For example, but not by way of limitation, the key of
13 the second embodiment or the swivel joint of the third embodiment
14 may be used in either of the fourth and fifth embodiments.
15 Furthermore, the described handle assemblies may be used with
16 other surgical instruments where both axial and rotational
17 movement of a control member relative to a tubular member is
18 required. For example, the handle may be used in laparoscopic and
19 endoscopic instruments, generally, which include an end effector
20 other than a snare loop. For example, and not by way of
21 limitation, end effectors such as baskets and forceps may be used
22 with the handle. It will therefore be appreciated by those
23 skilled in the art that yet other modifications could be made to
24 the provided invention without deviating from its spirit and scope
25 as claimed.

4. A surgical instrument according to claim 1, wherein:
said first means is located distal said second means.

5. A surgical instrument according to claim 1, wherein:
said tubular member has proximal and distal ends, and
said first means is a first handle including a first member
and including a second member provided with a bore, said second
member being axially rotatable relative to said first member,
said first member having a distal end fixedly coupled to said
proximal end of said sheath and a proximal end coupled to said
distal end of said tubular member,

 said shaft extending through said bore, and said second
member having means for engaging said shaft such that rotation of
said second member relative to first member causes rotation of
said shaft relative to said sheath.

6. A surgical instrument according to claim 5, wherein:
 said shaft includes a key portion provided with a non-
 circular cross section, and said means for engaging said shaft is
 a non-circular cross section of said bore of said second member
 adapted to engage said key portion.

11. A surgical instrument according to claim 1, wherein:
said shaft comprises a first element extending from said end effector to a location proximal said first means, and a second element extending from said location to said second member of said second means, said first and second elements being freely axially rotatable relative to each other.
12. A surgical instrument according to claim 11, wherein:
said first and second elements are coupled by a swivel joint.
13. A surgical instrument according to claim 11, wherein
said first element of said shaft is camber-free.
14. A surgical instrument according to claim 1, wherein:
said shaft is freely axially rotatable relative to said second means.
15. A surgical instrument according to claim 14, wherein:
said shaft is camber-free.

20. A surgical instrument according to claim 18, wherein:
said mounting means is adapted to adjustably fix said distal end of said sheath relative to a distal end of the endoscope.

21. A surgical instrument for insertion through an endoscope having a handle and a working channel, said surgical instrument comprising:

- a) a elongate flexible tubular sheath having proximal and distal ends;
- b) a flexible shaft extending through and axially movable relative to the sheath, said shaft having proximal and distal ends;
- c) an end effector coupled to or formed at said distal end of said shaft, said end effector capable of being positioned in open and closed positions; and
- d) a handle including coupling means for coupling said handle to the endoscope handle, and further including,
 - i) first means for longitudinally moving said sheath relative said working channel of the endoscope,
 - ii) second means for longitudinally moving said shaft relative to said sheath such that said end effector is movable between open and closed positions determined by relative positions of said sheath and said shaft, and
 - iii) third means for axially rotating said shaft relative to said sheath.

28. A surgical instrument according to claim 21, wherein:
said shaft is freely axially rotatable relative to said third
means.

29. A surgical instrument according to claim 28, wherein:
said shaft is camber-free.

30. A surgical instrument according to claim 21, further
comprising:

e) means for providing a cautery current to said shaft.

31. A surgical instrument for insertion through an endoscope
having a handle and a working channel, said surgical instrument
comprising:

a) a elongate flexible tubular sheath having proximal and distal
ends;

b) a flexible shaft extending through and axially movable
relative to the sheath, said shaft having proximal and distal
ends;

c) an end effector coupled to or formed at said distal end of
said shaft;

d) a first means for rotating said shaft relative to said
sheath;

e) a second means for longitudinally moving said shaft relative
to said sheath; and

36. A surgical instrument according to claim 31, wherein:
said first means is located distal said second means, and
said shaft comprises a first element extending from said end
effector to a location proximal said first means, and a second
element extending from said location to said second means, said
first and second elements being freely axially rotatable relative
to each other.

37. A surgical instrument according to claim 36, wherein:
said first and second elements are coupled by a swivel joint.

38. A surgical instrument according to claim 36, wherein
said first element of said shaft is camber-free.

39. A surgical instrument according to claim 31, wherein:
said shaft is freely axially rotatable relative to said
second means.

40. A surgical instrument according to claim 39, wherein:
said shaft is camber-free.

41. A surgical instrument according to claim 31, further
comprising:
e) means for providing a cautery current to said shaft.

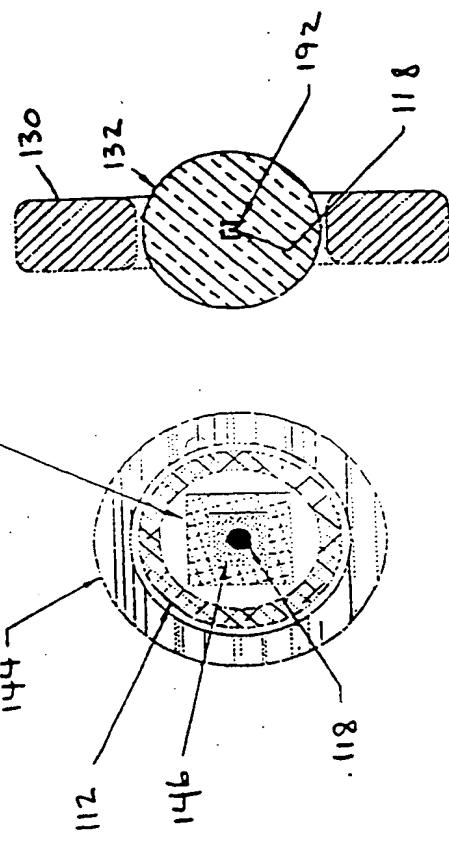
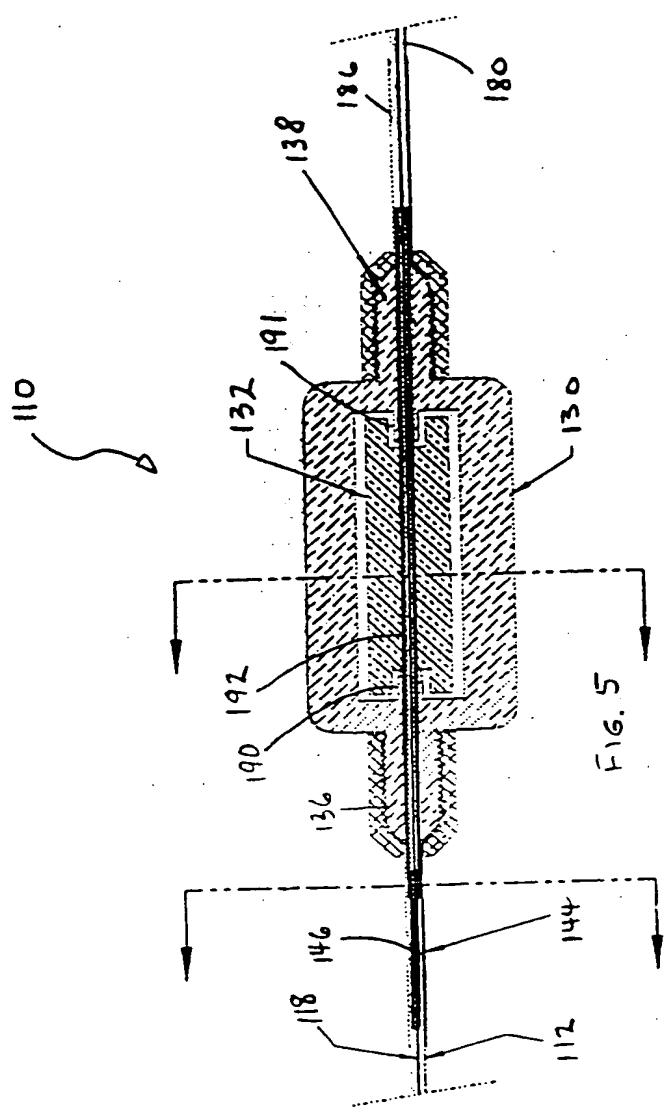


Fig. 7

